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Docket No. ORT-1552

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Andrew Darrow, et al.

Serial No. : 10/015,989 Art Unit: Not Assigned

Filed : December 10, 2001 Examiner: Not Assigned

For : ZYMOGEN ACTIVATION SYSTEM

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, Washington, D.C. 20231 on

11-20-02
(Date of Deposit)

Ralph R. Palo
(Name of applicant, assignee, or Registered Representative)

[Signature]
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11-20-02
(Date of Signature)

Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☒ In view of the voluminous nature of the following references which are of record in the **Parent Application Serial No.: 09/386,642**, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith for:

US 4,992,373
US 5,196,322
US 5,200,340
US 5,217,878
US 5,270,178
US 5,278,062
US 5,326,700
US 5,342,762
US 5,665,566
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J. Kyte and R. F. Doolittle, "A Simple Method for Displaying the Hydropathic Character of a Protein", J. Mol. Biol. (1982) 157:105-132.

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B. Martoglio and R. Dobberstein, "Signal Sequences: More Than Just Greasy Peptides", Trends Cell Biol. (1998) 8:410-415.

Matthews et al., "Three-Dimensional Structure of Tosyl-.alpha.-Chymotrypsin", Nature (London) (1967) 214:652-656.

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W. R. Pearson and D. J. Lipman, "Improved Tools for Biological Sequence Comparison", P. N. A. S. USA

(1988) 85:2444-2448.

Pham et al., "Production of Fully Active Recombinant Murine Granzyme B in Yeast", J. Biol. Chem. (1988) 273(3):1629-1698.

D. Proud and A. P. Kaplan, "Kinin Formation: Mechanisms and Role in Inflammatory Disorders", Ann. Rev. Immunol. (1988) 6:49-83.

N. D. Rawlings and A. J. Barrett, "Families of Serine Peptidases", Methods Enzymol. (1994) 244:19-61.

K. B. M. Reid and R. R. Porter, "The Proteolytic Activation Systems of Complement", Ann. Rev. Biochem. (1981) 50:433-464.

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K. Tachias and E. L. Madison, "Converting Tissue-Type Plasminogen Activator into a Zymogen", J. Biol. Chem. (1996) 271:28749-28752.

Takayama et al., "Characterization of the Precursor of Prostate-Specific Antigen Activation by Trypsin and by Human Glandular Kallikrein", J. Biol. Chem. (1997) 272:21582-21588.

Wang et al., "Production of Active Recombinant Human Chymase from a Construct Containing the Enterokinase Cleavage Site of Trypsinogen in Place of the Native Propeptide Sequence", Biol. Chem. Hoppe-Seyler (1995) 376:681-684.

Yamashiro et al., "Molecular Cloning of a Novel Trypsin-Like Serine Protease (Neurosin) Preferentially Expressed in Brain", Biochim. Biophys. Acta (1997) 1350:11-14.

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Yoshida et al., "cDNA Cloning and Expression of a Novel Serine Protease, TLSP1", Biochim. Biophys. Acta (1998) 1399:225-228.

Yu et al., "Molecular Cloning: Tissue Specific Expression and Cellular Localization of Human Prostatic mRNA", J. Bio. Chem. (1995) 270(22): 13483-13489.

Yu et al., "Prostatic is a Novel Human Serine Proteinase from Seminal Fluid: Purification, Tissue

Distribution and Localization in Prostate Gland", J. Biol. Chem. (1994) 269:18843-8.

☒ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ There are no listed references which are not in the English language.

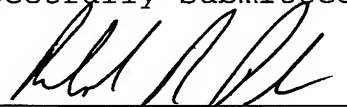
☐ The relevance of those listed references which are not in the English language is as follows:

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/ORT-1552/RRP. This form is submitted in triplicate.

Respectfully submitted,



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Reg. No. 29,486
Attorney for Applicants

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DATED:



Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Application Number	10/015,989
Filing Date	10 December 2001
First Named Inventor	DARROW
Group Art Unit	Not Assigned
Examiner Name	Not Assigned
Attorney Docket Number	ORT-1552

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. 1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
		4,992,373		Bang et al.	02-12-1991	
		5,196,322		Bang et al.	03-23-1993	
		5,200,340		Forster et al.	04-06-1993	
		5,217,878		Van Eekelen et al.	06-08-1993	
		5,270,178		Gerlitz et al.	12-14-1993	
		5,278,062		Samal et al.	01-11-1994	
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		5,342,762		Mosher et al.	08-30-1994	
		5,665,566		Lavallie, Edward R.	09-09-1997	
		5,834,247		Comb et al.	11-10-1998	
		5,726,038	A	Christiansen	03-10-1998	
		5,504,001	A	Foster	04-02-1996	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. 1	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵				
		EP	0887414		SmithKline Beecham PLC	12-30-1998		
		WO	97/47737		Boehringer Mannheim GmbH	12-18-1997		
		WO	98/49326		Symbiosis Genetics, Inc.	11-05-1998		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		ALTSCHUL ET AL., (1990) Basic Local Alignment.	
		I. AUSUBEL AND M. FREDERICK, "Short Protocols in Molecular Biology", Molecular biology-Laboratory Manuals (1997).	
		CHEN ET AL., "Expression and Activity-Dependent Changes of a Novel Limbic-Serine Protease Gene in the Hippocampus", <i>J. Neurosci.</i> (1995) 15: 5088-5097.	
		DAVIE ET AL., "The Coagulation Cascade: Initiation, Maintenance, and Regulation.", <i>Biochemistry</i> (1991) 30:10363-10370	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

Application Number	10/015,989
Filing Date	10 December 2001
First Named Inventor	DARROW
Group Art Unit	Not Assigned
Examiner Name	Not Assigned
Attorney Docket Number	ORT-1552

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		HANSSON ET AL., "Cloning, Expression, and Characterization of Stratum Corneum Chymotryptic Enzyme: A Skin-Specific Human Serine Proteinase", <i>J. Biol. Chem.</i> (1994) 269:19420-19426.	
		R. HUBER AND W. BODE, "Structural Basis of the Activation and Action of Trypsin", <i>Acc. Chem. Res.</i> (1978) 11:114-122.	
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		J. KYTE AND R. F. DOOLITTLE, "A Simple Method for Displaying the Hydrophobic Character of a Protein", <i>J. Mol. Biol.</i> (1982) 157:105-132.	
		LEYTUS ET AL., "A Novel Trypsin-Like Serine Protease (Hepsin) with a Putative Transmembrane Domain Expressed by Human Liver and Hepatoma Cells", <i>Biochemistry</i> (1988) 27:1067-1074.	
		LITTLE ET AL., "Zyme, A Novel and Potentially Amyloidogenic Enzyme cDNA Isolated from Alzheimer's Disease Brain", <i>J. Biol. Chem.</i> (1997) 272:25135-25142.	
		B. MARTOGLIO AND R. DOBBERSTEIN, "Signal Sequences: More Than Just Greasy Peptides", <i>Trends Cell Biol.</i> (1998) 8:410-415.	
		MATTHEWS ET AL., "Three-Dimensional Structure of Tosyl- α -Chymotrypsin", <i>Nature (London)</i> (1967) 214:652-656.	
		NELSON ET AL., "Molecular Cloning and Characterization of Prostase, An Androgen-Regulated Serine Protease with Prostate-Restricted Expression", <i>P. N. A. S. USA</i> (1999) 96:3114-3119.	
		W. R. PEARSON AND D. J. LIPMAN, "Improved Tools for Biological Sequence Comparison", <i>P. N. A. S. USA</i> (1988) 85:2444-2448.	
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		D. PROUD AND A. P. KAPLAN, "Kinin Formation: Mechanisms and Role in Inflammatory Disorders", <i>Ann. Rev. Immunol.</i> (1988) 6:49-83.	
		N. D. RAWLINGS AND A. J. BARRETT, "Families of Serine Peptidases", <i>Methods Enzymol.</i> (1994) 244:19-61.	
		K. B. M. REID AND R. R. PORTER, "The Proteolytic Activation Systems of Complement", <i>Ann. Rev. Biochem.</i> (1981) 50:433-464.	
		SAMBROOK ET AL., <i>Molecular Cloning: A Laboratory Manual</i> , 2 nd Ed. (Cold Spring Harbor Laboratory, Cold Spring Harbor, N.Y. (1989)).	
		SHERMAN ET AL., "Identification of Tissue-type Plasminogen Activator-specific Plasminogen Activator Inhibitor-1 Mutants", <i>J. Biol. Chem.</i> (1995) 270(16):9301-9306.	
		STROUD ET AL., "Structure of Bovine Trypsin: Electron Density Maps of the Inhibited Enzyme at 5 .ang. and 2.7 .ang. Resolution", <i>J. Mol. Biol.</i> (1974) 83:185-208.	
		K. TACHIAS AND E. L. MADISON, "Converting Tissue-Type Plasminogen Activator into a Zymogen", <i>J. Biol. Chem.</i> (1996) 271:28749-28752.	
		TAKAYAMA ET AL., "Characterization of the Precursor of Prostate-Specific Antigen Activation by Trypsin and by Human Glandular Kallikrein", <i>J. Biol. Chem.</i> (1997) 272:21582-21588.	
		WANG ET AL., "Production of Active Recombinant Human Chymase from a Construct Containing the Enterokinase Cleavage Site of Trypsinogen in Place of the Native Propeptide Sequence", <i>Biol. Chem. Hoppe-Seyler</i> (1995) 376:681-684.	
		YAMASHIRO ET AL., "Molecular Cloning of a Novel Trypsin-Like Serine Protease (Neurosin) Preferentially Expressed in Brain", <i>Biochim. Biophys. Acta</i> (1997) 1350:11-14.	
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		YU ET AL., "Molecular Cloning: Tissue Specific Expression and Cellular Localization of Human Prostatin mRNA", <i>J. Bio. Chem.</i> (1995) 270(22): 13483-13489.	
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Examiner Signature	Date Considered
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